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(54) Ostomy appliance

(57) An ostomy appliance including a bag having a resealable opening at the top just above the stomal opening which permits the ostomate to clean and redress the area contiguous to the stoma without removing the appliance. The bag can also include a resealable bottom closure for drainage and an adhesive mounting gasket around the stomal opening.

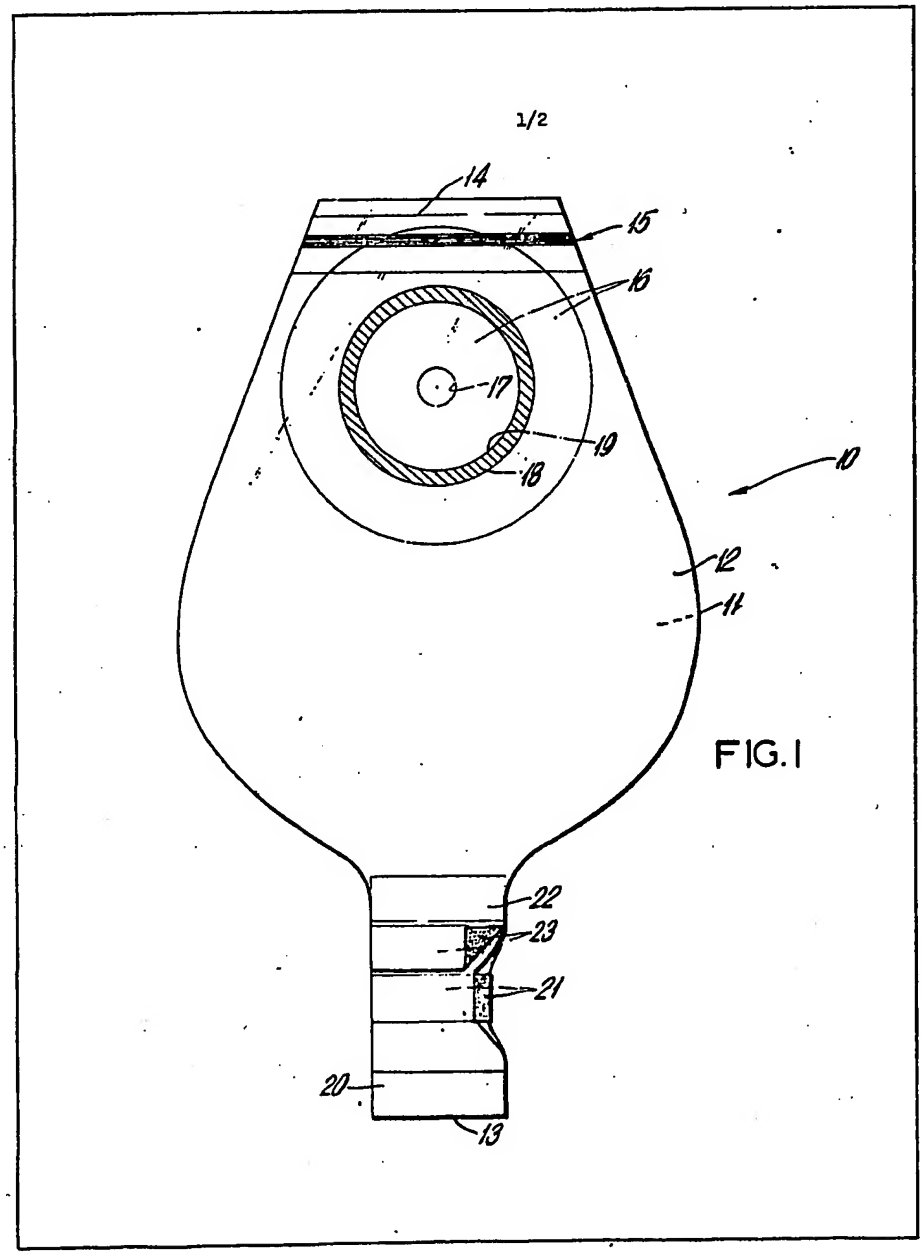

FIG.1

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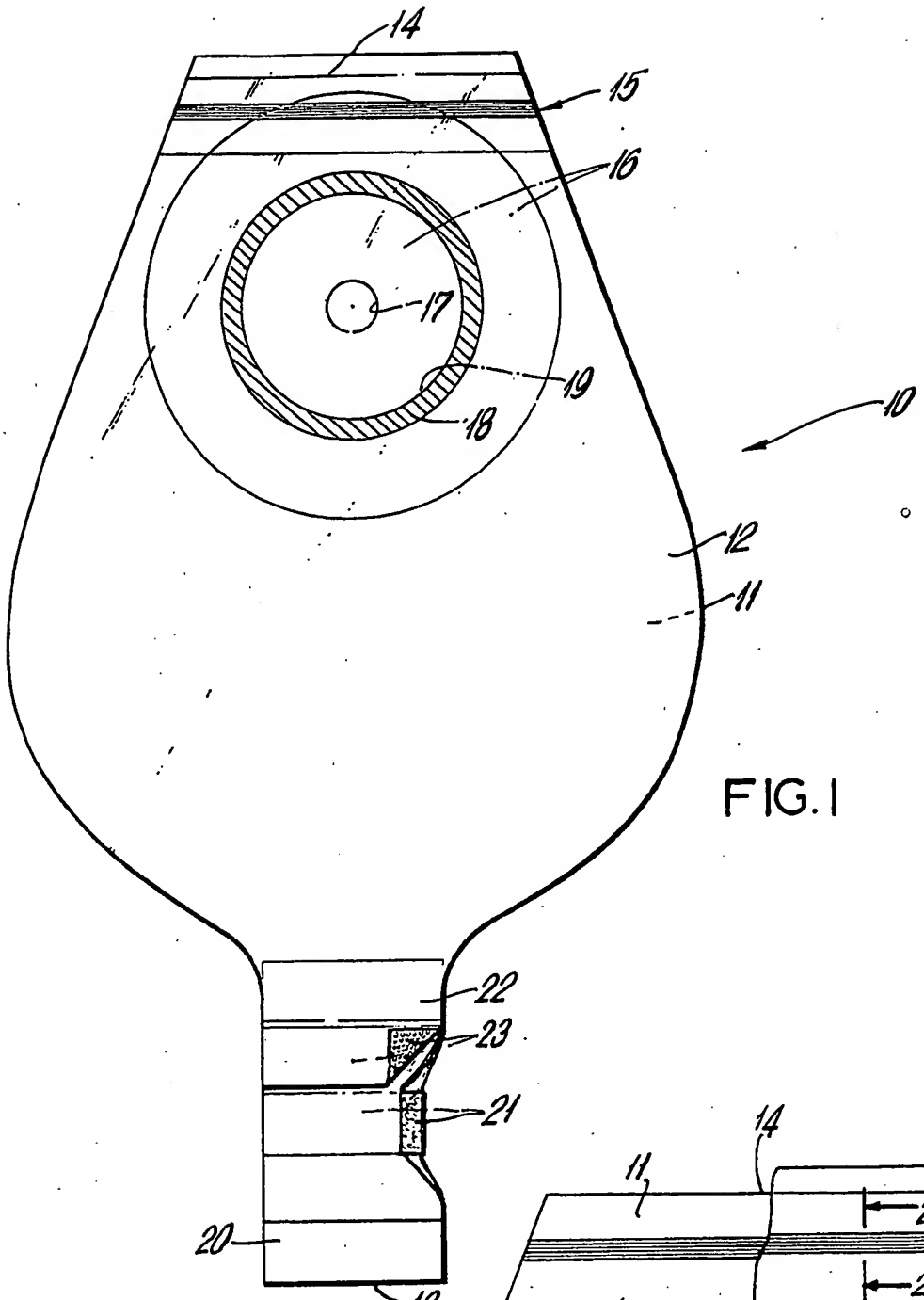

FIG. 1

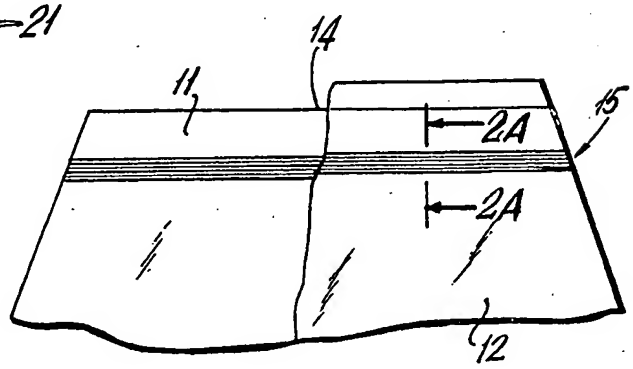

FIG. 2

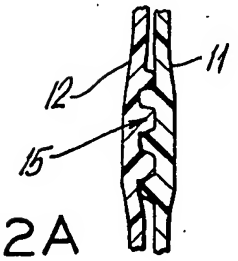

FIG. 2A

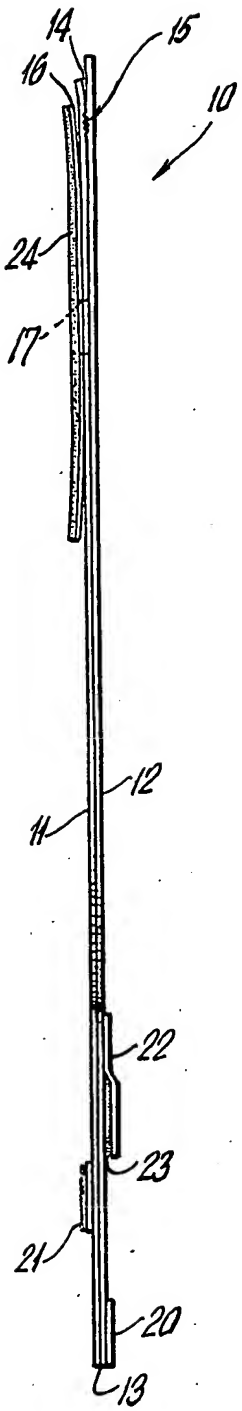

FIG. 3

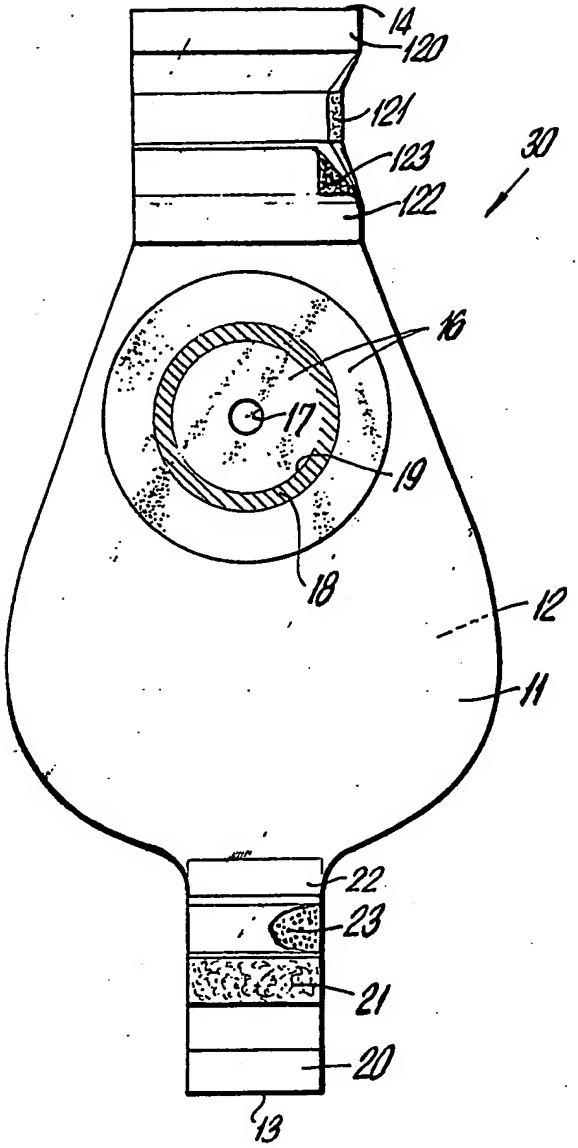

FIG. 4

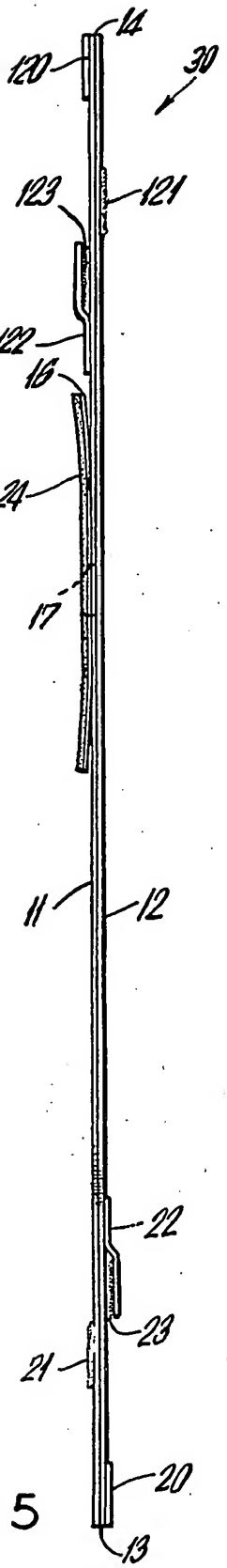

FIG. 5

SPECIFICATION

Ost my appliance

This invention is directed to an ostomy appliance permitting access to the stoma through a resealable opening located at the top of the bag and an easy to use seal at the bottom of the bag for draining. By means of the top opening the ostomate is able to examine and irrigate or clean the skin around the stoma and pack this area with medicinal powder or ointment without first having to remove the appliance. Also, the top opening enables the ostomate to fit the appliance around the stoma with greater ease.

Figure 1 is a front view of the outer side of an ileostomy appliance including a bag having a resealable opening across the top and a drainage closure at the bottom.

Figure 2 is an exploded enlarged view of the resealable top opening shown in Fig. 1.

Figure 2A is a sectional view taken along lines 2A—2A of Fig. 2.

Figure 3 is a side elevation of the appliance shown in Fig. 1.

Figure 4 is a front view of the skin side of an ileostomy appliance employing the same type of resealable means as both the top opening and bottom closure.

Figure 5 is a side elevation of the appliance shown in Fig. 4.

Ostomy appliance and in particular the one-piece reusable or semi-permanent units described above that are commonly used by persons having an ileostomy or urinary stoma present several problems. These units whether affixed directly to the body or to a skin barrier are designed to remain in place for about 7 to 14 days.

However, the flow of effluent from the stoma can erode the adhesive material of the appliance or of the skin barrier adjacent to the stoma thus lessening the length of time for which the unit can remain in place. This breakdown is accelerated if the appliance is improperly fitted around the stoma. The effluent can then contact the unprotected skin contiguous with the stoma and cause serious irritation.

This invention is directed to means enabling the ostomate to examine and clean the area of skin contiguous with the stoma and, if necessary, redress this area with an ostomy powder or ointment without the necessity of first r moving the appliance. By so treating, the rate of erosion of the adhesive and the skin barrier are reduced and the appliance can remain in place for a longer period of time. This result is achieved by providing a r s alable opening at the top of bag above the stomal opening.

Also, this invention is directed to a bottom closure means enabling the ostomate to easily drain the bag.

For convenience this invention will be described as it would be employed with a one-piece semi-permanent ileostomy appliance. However, by modifications that will be described below, the invention is also applicable to appliances for a colostomy or urinary stoma as well as a one-piece reusable or two-piece ileostomy appliance.

An ileostomy appliance 10 incorporating the features of this invention is shown in Figs. 1 to 3. The appliance 10 includes a bag having polymeric film surfaces 11 and 12 permanently sealed along a majority of their edges by heat or other means known in the art. Sides 11 and 12 are not joined along either the bottom edge 13 or top edge 14. Side 11 is the skin side of the appliance and side 12 is the outer side. There is an opening 19 in sidewall 11 through which the stoma protrudes.

The film surfaces 11 and 12 can be formed from any suitable polymeric material which is moisture proof and odor proof and has the necessary strength. Suitable materials include polyethylene, a copolymer of vinyl chloride and polyvinylidene chloride, etc., and laminates thereof such as a laminate of ethylene vinylacetate or polyethylene and a copolymer of vinyl chloride and polyvinylidene chloride. Both polymeric film surfaces 11 and 12 can be clear or opaque or the skin side 11 can be clear and outside 12 opaque. The thickness of the films 11 and 12 will vary depending upon the particular polymeric material but generally will range from about 2 to about 8 mils.

A mounting gasket or faceplate comprising a flexible film 16 of rubber or polymeric material and a pressure sensitive adhesive layer 24 (note figure 3) is permanently bonded by heat, adhesive, or other known means to skin side 11 around opening 19. The area of the bond between the faceplate and side 11 is represented as cross-hatched area 18 in Fig. 1. As can be seen in Fig. 3, the outer peripheral edge of the faceplate is free from side 11 and can thus conform to the body of the ostomate. A starter hole 17 is provided in the faceplate. The ostomate increases the size of the starter hole 17 according to the diameter of the stoma. Of course, the bonding area 18 must remain intact. Preferably, the faceplate is a film 16 of polymeric material such as polyethylene of from about 1 to about 5 mils in thickness having as the adhesive composition 24 a homogeneous mixture of polyisobutylene, sodium carboxymethylcellulose, gelatin and pectin as taught by Chen in U.S. Patent 3,339,546 at from about 50 to about 150 mils thickness. The faceplate is normally disk shaped as shown in Fig. 1 but can be formed in other shapes such as rectangular if desired. Optionally, a ring shaped pressure plate (not shown in the drawings) having a belt

attachment can be fitted between the faceplate and surface 11. Also, during shipping the exposed surface of the adhesive layer 24 is covered by a piece of silicone coated release paper.

The resealable opening means 15 near the stomal opening is shown in Figs. 1 and 3 and in greater detail in Figs. 2 and 2A. As shown in Figs. 2 and 2A, alternate rows of raised ridges separated by grooves are present on the inside of polymeric surfaces 11 and 12. The rows are aligned so that the raised ridges on the inside of film 12 can be forced by the exertion of a slight amount of pressure into a groove on the inside of surface 11. The seal formed is fluid and odor tight. Methods of forming this and other equivalent types of interlocking surfaces on polymeric films are taught in various references such as by Kraus in U.S. Patent 3,380,481, Ausnit in U.S. Patent 3,371,696, by Naito et al in U.S. Patents 3,198,228 and 3,246,672 and by Goto in U.S, Patent 3,462,332. As shown in Figs. 2 and 3 the upper edge of film surface 12 extends beyond the upper edge of film surface 11 so as to aid in pulling the two surfaces apart.

The appliance 10 includes a resealable closure at the bottom of the bag which permits the bag to be emptied through opening 13. The bottom closure as shown in Figs. 1 and 3 includes polymeric film member 22 bonded by adhesive or other means to the outer bag surface 12 at the top of the tail portion of the bag. A section of hook type male elements 23 are bonded to the inside of film 22 facing bag surface 12 as shown in Fig. 3 and the folded back edge in Fig. 1. A section of female loop elements 21 are bonded to the skin side of the bag surface 11. The method of forming such male and female elements is taught by deMestral in U.S. Patent 3,009,235. A bar 20 of relatively rigid polymeric material is bonded to the bottom of surface 12. The seal is formed by bending film 22 back and folding bar 20 over itself so that the loops 21 are facing outward away from the body. Hook elements 23 are then pressed into contact with loops 21 to complete the seal. Of course, the film member 22 and bar 20 can be attached to polymeric surface 11 and loop elements 21 attached to surface 12 if desired.

An alternative type of resealable opening at the top of the bag portion of appliance 30 is shown in Figs. 4 and 5. This embodiment employs the same closure at both the top and the bottom of the bag. As shown best in Fig. 5, a polymeric film 122 is attached to film surface 11 just above the faceplate with male hook elements 123 facing film surface 11. The female loop elements are attached to the outside of film surface 12 and a relatively rigid polymeric bar element is attached to the top of film surface 11. The seal is formed by bending back film 122 and folding bar 120 over itself so that the loops 121 are facing toward the body. Hook elements 123 are then pressed into contact with loops 121 to complete the seal. This top sealed portion of the bag can then be rolled down and placed between the faceplate and polymeric film surface 11. Of course, the film member 122 and bar 120 can be attached to polymeric film 12 and loop elements 121 attached to surface 11 if desired. As shown in Fig. 4, the opening at the top edge 14 of the bag is of greater width than the bottom opening 13 so that it is easier for the ostomate to reach down into the bag and treat the skin contiguous to the stoma.

Ileostomy appliances 10 and 30 are employed in essentially the same manner. The ileostomate enlarges the starting hole 17 according to the size of his stoma. The silicone coated release paper is removed. The area around the stoma is cleaned, dried, and dressed. The bottom closure is sealed but the top closure near the stoma remains open. The appliance is fitted with the top opening enabling the ileostomate to perform the fit with greater ease. The top closure is then sealed. At any time while the appliance is in place the ileostomate is able to open the top seal and examine the stomal area. If necessary, the area can be cleaned by use of a cotton swab passed down through the opening and the area can also be redressed with ointment or other medication. The opening is then resealed. Of course, at periodic intervals the bottom seal is opened to drain the contents of the bag.

This invention has been described with reference to a semi-premanent one-piece ileostomy appliance. However, it is also applicable to other ostomy appliances. For example, the adhesive layer 24 can be omitted so that the faceplace is merely a film of polymeric material and a separate double sided pressure sensitive adhesive disk is employed to mount the appliance. In the case of a urinary stoma, the bottom Velcro (Registered Trade Mark) type closure can be replaced by a valve means as shown by Nolan in U.S. Patent 3,822,704. In the case of a colostomy, the bottom of the bag would be sealed. Also, the bag can include a deodorizing and/or vent means as disclosed, for example, by Riely in U.S. Patent 3,690,320, by Nolan et al. in U.S. Patent 3,759,260 and by Elmore et al. in U.S. Patent 3,865,109.

CLAIMS

1. An ostomy appliance comprising a bag formed from two polymeric film surfaces permanently sealed along a majority of their length, resealable opening means at both the top and bottom edges of said bag, one of said polymeric film surfaces being the skin side of

the bag and having an opening which fits around the stoma, the other polymeric film surface being th outer side of the bag, said resealable bottom opening means comprising a section of male hook elements attached to one of said polymeric film surfaces and a section of female loop elements attached to the other polymeric film surface, and wherein said resealable top opening means is above said stomal opening and provides access for the ostomate to the area contiguous to the stoma without the need for removal of the appliance.

2. The appliance of claim 1 wherein said resealable top opening means comprises interlocking surfaces on the inside of each polymeric film surface.

3. The appliance of claim 2 wherein said interlocking surfaces are a series of alternating raised ridges and grooves extending across the top of said bag which are aligned so that by the exertion of a small amount of pressure the raised ridge on the inside of one surface will fit within the groove on the inside of the other surface.

4. The appliance of claim 3 including a faceplate of a flexible film of rubber or polymeric material which is permanently bonded to the skin side of the bag around said stomal opening, said faceplate having a centrally located opening which is expanded by the ostomate to fit snugly around the stoma.

5. The appliance of claim 4 wherein said bottom opening means comprises a polymeric film member having male hook elements on its inner surface said polymeric film member permanently bonded to the outer side of the bag such that the hook elements face the bag, female loop elements permanently bonded to the skin side of the bag, and a bar of relatively rigid polymeric material permanently bonded to the bottom of the outer side of the bag whereby the seal is formed by bending the bar back over itself so that the femal loop and male hook elements can be pressed together.

6. The appliance of claim 5 wherein said faceplate comprises a thin disk shaped film of polymeric material having a layer of pressure sensitive adhesive on its exposed surface and wherein the bond between said disk shaped film and said skin side of the bag does not extend to the outer peripheral edge of said faceplate.

7. The appliance of claim 6 wherein said faceplate comprises a thin film of polyethylene having as the pressure sensitive adhesive a homogeneous mixture of gelatin, pectin, sodium carboxymethylcellulose, and polyisobutylene.

8. The appliance of claim 1 wherein said resealable top opening means comprises a section of male hook elements attached to one of said polymeric film surface and a section of female loop elements attached to the other polymeric film surface.

9. The appliance of claim 8 including a faceplate of a flexible film of rubber or polymeric material which is permanently bonded to the skin side of the bag around said stomal opening, said faceplate having a centrally located opening which is expanded by the ostomate to fit snugly around the stoma.

10. The appliance of claim 9 wherein said resealable opening comprises a polymeric film member having male hook elements on its inner surface said polymeric film member permanently bonded to the skin side of the bag just above the faceplate so that the hook elements face the bag, female loop elements permanently bonded to the outer side of the bag, and a bar of relatively rigid polymeric material permanently bonded to the top of the skin side of the bag whereby the seal is formed by bending the bar back over itself so that the female loop and male hook elements can be pressed together.

11. The appliance of claim 10 wherein said bottom opening means comprises a polymeric film member having male hook elements on its inner suface said polymeric film member permanently bonded to the outer side of the bag so that the hook elements face the bag, female loop elements permanently bonded to the skin side of the bag, and a bar of relatively rigid polymeric material permanently bonded to the bottom of the outer side of the bag whereby the seal is formed by bending the bar back over itself so that the femal loop and male hook elements can be pressed together.

12. The appliance of claim 11 wherein said faceplate comprises a thin disk shaped film of polymeric material having a layer of pressure sensitive adhesive on its exposed surface and wherein the bond between said disk shaped film and said skin side of the bag does not extend to the outer peripheral edge of said faceplate.

13. The appliance of claim 12 wherein said faceplate comprises a thin film of polyethylene having as the pressure sensitive adhesive a homogeneous mixture of gelatin, pectin, sodium carboxymethylcellulose, and polyisobutylene.

14. An ostomy appliance substantially as herein described with reference to and as illustrated in the accompanying drawings.

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